REMARKS

Preamble

Accurate definitions of "data" and "software"

In discussing and comparing the prior art and the present invention, it is important to differentiate between "data" and "software", since this difference is crucial in the analysis and explanation of differences between the cited prior art and the present invention.

"Data" refers to patient measurements or patient records that are specific to a patient, and vary from patient to patient. It is the *output* or *result* of a *measurement* process or *patient-specific operator input*. Such information is usually transferred or stored for the purposes of visual representation, printing, record-keeping, and similar such purposes.

"Software" or "Programs" or "Code" refer to *executable code* or *instructions executed* by a central processing unit or computer for the purposes of *controlling hardware* or *processing* data with a given algorithm. Software does not vary from patient to patient, but *defines the device, its function and control*.

While "data communications" can, in general, involve the transfer of any digital content represented by ones and zeroes - be it software, programs or data, the *context* of a given disclosure or discussion of a given physical system usually indicates whether a given communications channel is to be used for "data" or "software" or both. This is further clarified by the *structure* of the machine itself. In many cases, the specification and drawings will show a general machine that can modify its own memory *or* data and is therefore *completely flexible;* or a machine that can modify and transfer *data*, but the *program cannot be modified* by the content of a data channel. In short, while "data communication" is a general statement of transmission of any information represented by ones and zeroes, the *context* of the use of the term will usually indicate whether the information is "data" or "software/program".

The suggestions, disclosures and specifications of medical devices is further clarified by the *regulatory environment* which is *well-understood by those skilled in the art*. It is

well-known that regulatory bodies enforce tight controls on the specification, development, and functionality of *software* used in medical devices. Specifically, the U.S. Food and Drug Administration (FDA) places tight controls on medical device software. It is thus *counter-intuitive to those skilled in the art that any inventor or developer would provide a means for modifying the software on a small, portable medical device*. In most cases, modification of medical device software would render the device illegal for use in the United States, and in most other countries.

The context of all the above terminology and the medical environment in which it is used is critically important in evaluating the prior art, and whether a given invention discloses a means to modify "data" or "software"/"programs" or both.

These definitions are crucial to the comparison between the prior art, and analysis of the novelty of the present invention with respect to such prior art.

"Data" used in Prior Art Reference Bredesen (US 5,010,889)

Specifically, Examiner cites Bredesen (US 5,010,889) as a central prior art reference, and in particular the use of a "data port" as suggesting or anticipating the present invention. It is essential to apply the above concepts of "data" and "software" to Bredesen, or order to understand the prior art, place it in context, and differentiate it from the present invention. It will be shown that Bredesen's disclosure and drawings clearly indicate that "data" is being transferred, rather than "software". This is a critical difference between Bredesen and the present invention.

Bredesen's disclosure of the functions and purpose of a data port are as follows:

> "There is also a peripheral data port (not shown) which is used for the transfer of data base memory to a digital plotter, and/or storage in a larger memory media." (Examiner's reference Bredesen Col 3, lines 23-29).
>
> "The intelligent stethoscope system also has a four wire interface for serial communication to dedicated peripherals shown in FIG. 3b. These peripherals would

be used for plotting cardiac waveforms, or storage of the waveform data base memory for future retrieval. The I/O interface circuit U2 of FIG. 3b uses its programmable I/O lines to generate two output lines and one input line for the peripheral interface." (Bredesen Col 7, lines 42-55).

To further understand Bredesen's disclosure, the description of drawings of the invention are instructive. Bredesen discloses *separate program memory* using UV Erasable Programmable Read-Only Memory (EPROM) (Fig. 2, 217 and Fig. 3B, U4 industry part number 27C128) and *data base memory* using Random Access Memory (RAM) (Fig. 2, 219 and Fig. 3D, U5 industry part number HM62256LP). It is well-understood by those skilled in the art that such a circuit conceptually and in physical embodiment *does not provide for modification of the program or software* through the use of "said (not shown) data port."

Consistent with this limitation, Bredesen's above disclosures state that the data port is intended for the *transfer of the contents of "data base memory"* i.e. the *RAM*, not the EPROM. This is further clarified by Bredesen stating that the *content* of the data transfer is for the purposes of *plotting or storage* in a larger media, which implies archiving of patient *data* for record-keeping purposes, since *software code is not plotted*. In the second referenced paragraph quoted above, Bredesen describes a bi-directional data flow capability, suggesting that archived data could be *loaded back into the device's RAM*, presumably for visual display.

A reader skilled in the art would understand clearly from both description and the detailed schematic diagrams that:

(a) Program or Code memory is *not writeable by the microprocessor*, and certainly is not writeable from a data stream entering the "data port".
(b) *Data memory* is transferable via the data port, however "data" is clearly *recorded measurement* i.e. information to be viewed and plotted, and archived in medical records - clearly *not* software or program code.

A reader skilled in the art would thus see that clearly the *hardware is incapable of modifying software*, and that the disclosure uses the term "data" to mean *exclusively*

measurement information, not software or program instructions. Bredesen further *makes no suggestion that software or program code can or should be modified.* This is clearly *consistent* with what is well understood to those skilled in the art - that *modification of medical device software is counter-intuitive and usually undesirable.*

Since Bredesen is a central Examiner reference in the prior art, the above discussion provides a foundation for further discussion of Examiner's rejection of the claims of the present invention, as discussed below in further detail, along with other Examiner references.

Detailed Discussion of Claim Rejections

(The following discussion is numbered consistently with Examiner's remarks.)

Discussion of Claim Rejections 35 U.S.C. 102

2. "Claims 19, 23, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bredesen et al. US Patent 5,010,889 (hereinafter, "Bredesen")

Highlighting the differences between Claim 19 and Bredesen:

"Wherein software programs can be downloaded via digital communication means, stored in digital memory, and executed by central processing unit." (Claim 19) -

As discussed in the above Preamble, Bredesen neither suggests nor shows a method for *downloading software* (as opposed to data) into the stethoscope to be executed by the central processing unit in the stethoscope. The software in Bredesen's invention is stored in *memory that is not modifiable by the central processing unit or data port* and is therefore different from the digital memory claimed in claim 19.

Examiner cites Bredesen Col. 10 line 65 - Col. 11, line 40 in the context of the above claim element. Bredesen *teaches away* from Claim 19, by disclosing the possibility of downloading software "into a co-processor at another physical location" rather than the stethoscope central processing unit itself. Here again, Bredesen is not suggesting that it is desirable to download software into

the stethoscope, as stated in Claim 19 of the present invention.
"wearable" (Claim 19) -

Bredesen Fig.1 (100) shows a stethoscope design. Given the physical scale of Bredesen's invention, it is not suggested that the invention is wearable around the neck. The assumption that Bredesen's invention is wearable is not clearly supported by the specification.

Teaching Away

Bredesen specifically teaches away from the present invention by suggesting that downloading should be done to a *different processor in a different location* from the stethoscope. There is no suggestion at all as to the possibility or physical means for modifying the stethoscope software as claimed in Claim 19.

Claimed Features Lacking

Bredesen discloses a data communications means for transferring only "data". There is no feature, method, or suggestion for transferring "software" as claimed in Claim 19.

As to wearability, Bredesen makes no reference to wearability, and the drawings suggest a rather large form factor unsuited to being worn "around the neck or shoulders" as claimed in Claim 19.

Claim 23 is dependent on Claim 19.

Claim 31 is dependent on Claim 19.

Discussion of dependent claims 23 and 31 are encompassed by the above discussion of independent claim 19 above.

Discussion of Claim Rejections 35 U.S.C. 103

4. "Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen").

"digital memory means is non-volatile memory selected from the group Flash Memory, EERPOM, battery-backed RAM" (Claim 20) -

Examiner cites Bredesen's disclosure of EPROM memory as suggesting EEPROM would be an obvious choice to those skilled in the art. Examiner acknowledges that *Bredesen makes no explicit disclosure of the memory technologies listed in Claim 20.*

To those skilled in the art, EEPROM is *distinctly different* from EPROM, in that EPROM *cannot be modified electronically*, or by any operation *executed in software by the central processing unit* whereas EEPROM clearly provides this function. To modify EPROM, the memory device must be *physically removed* from the device, exposed to UV light, and re-programmed by an *external* programming device. Those skilled in the art select EEPROM for very explicit reasons - to provide electrically erasable memory *in a system*. As discussed above, Bredesen makes *no suggestion* that software re-programming is possible or desirable. Therefore the use of EEPROM would *not* be suggested by those skilled in the art. The combination of regulatory rules that discourage modification of medical device code, the additional cost, and the schematics showing *no means for writing to the EPROM*, indicate that Bredesen makes no suggestion to those skilled in the art as to the potential use of EEPROM, *or any other electronically re-writable technology* such as Flash or battery-backed RAM.

Bredesen takes the approach of using EPROM, without any facility for modifying the software, thereby taking a different approach from the present invention.

As stated by Examiner, Bredesen makes no mention of the non-volatile memories in Claim 20. Further, the data communications port does not provide means for moving software instructions into the program memory. The claimed features are therefore lacking in the present invention.

Bredesen makes no suggestion, either in the disclosure or the drawings, that writing to program memory is desirable. The use of difficult-to-modify memory teaches away from the claimed invention.

5. "Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent

5,010,889 (herinafter, "Bredesen") in view of Gavriely (US 6,261,238)."

"digital memory means is magnetic media with software program storage" (Claim 21) -

Gavriely discloses an opto-magnetic disk (col. 16 Lines 20-26):

> "The data storage device 22 can be used for storing certain selected segments of *digitally recorded sensor data* as well as the *results of the breath sound analysis*. It is noted that the digital storage device 22 can be any type of suitable digital data storage device such as a magnetic, optical, or magneto-optical digital data storage device."

As discussed in the Preamble, the distinction between "data" storage and "software" or "program" storage is critical to the difference between Gavriely and Claim 21. Gavriely clearly states that the intended content to be written to the opto-magnetic storage device is "sensor data" and "results of breath sound analysis". This is clearly "data" i.e. patient measurements or the results of an analysis rather than the analysis software itself.

As stated by Examiner, Gavriely's purpose is to store data for "archival purposes". This clearly refers to patient data that must be stored for long-term patient records. This is clearly different from the "software" referred to in independent Claim 19 of the present invention, and hence relevant to dependent Claim 21. Further differentiating the scope of Claim 21 from Gavriely, Claim 21 specifically claims "software program storage".

"wherein digital memory means is physically removable" (Claim 22) -

Claim 22 is dependent on Claim 19. Hence Gavriely's reference to "data" storage, not "software", the context and scope of independent Claim 19 pertains to the scope of Claim 22. As discussed, Bredesen also makes no reference to the "software programs" claimed in Claim 19. Since neither Bredesen nor Gavriely refer to software program memory, their combination leaves Claims 19, 22, and 23 unsuggested.

6. "Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Erten et al. U.S. Patent 6,236,862 (herinafter, "Erten")"

"wherein digital communications means is an infrared optical comuncations link" (Claim 24) -

As stated above, independent Claim 19 of the present invention differs markedly from Bredesen. As Examiner further acknowledges, Bredesen does not disclose an infrared digital communications means. Thus Bredesen does not disclose the elements of Claim 19 or dependent Claim 24.

Regarding Claim 24, Examiner cites Erten as disclosing optical communications. However, the subject matter of Erten is unrelated to the present invention, disclosing a *signal processing method for separating signal content when two signals are mixed.* This is *entirely different* from a digital communications channel for transferring software via an optical communications means. Erten discloses the use of his invention for potential use in stethoscopes, however this for the purpose of *separating signals such as heart and lung sounds or the maternal and fetal heartbeats when the sounds are mixed together* (Erten Col. 20 lines 40-50). Erten does not discuss digital memory, downloading of software, or transfer of data over a communications channel for the purposes of updating stethoscope software. Those skilled in the art would make no connection between Erten and the subject matter of either Bredesen or the present invention, and there is no suggestion in either Bredesen or Erten of their combination to suggest the present invention.

"wherein digital communications means is a wireless communications link" (Claim 25) -

Regarding Claim 25, Erten mentions wireless communication in the context of *signal separation algorithms.* Erten is addressing the problem of *inter-channel interference in the wireless spectrum,* and how his invention addresses that problem. This is entirely different subject matter to Claim 25 of the present invention which is wireless communication of *software to a stethoscope.* Erten mentions stethoscopes purely in relation to the problem of trying to separate

body sounds that interfere, *not* in relation to the method of communicating digital information to a stethoscope. Those skilled in the art would make no connection between Erten, Bredesen, and the present invention, and nothing in Erten or Bredesen suggests the present invention in any way.

"wireless communications means physically removable from from said electronic stethoscope housing" (Claim 26) -

Regarding Claim 26, Examiner agrees that Bredesen does not disclose a *physically removable* wireless communications means as claimed, arguing however, that removable components for the purpose of ease of modification are well-known and therefore obvious. However, the subject matter of the present invention is a stethoscope, and *stethoscopes have not been built as modular systems*. It is further *counter-intuitive to provide a means to modify a stethoscope, since regulatory requirements make it undesirable to provide user modification*. Claim 26 is further dependent on claim 19 which, as presented above, is not disclosed or suggested by Bredesen.

"digital communications means uses an 802.11 communications protocol" (Claim 27) -

Regarding Claim 27, as stated above, Erten discloses 802.11 wireless communication *with respect to inter-channel interference, the subject matter of which is unrelated and makes no suggestion of stethoscope software download channels*.

"digital communications means uses an Internet protocol selected from the group TCP/IP, FTP, PPP communications protocols" (Claim 28) -

Regarding Claim 28, as stated above, Erten discloses wireless communication protocols with respect to inter-channel interference, the subject matter of which is unrelated and makes *no suggestion of stethoscope software download channels*.

7. "Claims 29, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Iliff US Patent 6,236,862"

(Clarification of References: Examiner associates "Iliff" with U.S. Patent 6,236,862. This is incorrect. U.S. Patent 6,236,862 is Erten, discussed earlier. Examiner's remarks for "Iliff" appear to refer to Iliff U.S. Patent 6,022,315. Applicant therefore responds in "Iliff" in the context of U.S. Patent 6,022,315. Other Iliff patent numbers cover similar subject matter, however such patents are closely related to 6,022,315 and the same discussion pertains. Applicant is thus making a best effort to respond comprehensively to all Examiner remarks in light of this confusion.)

Regarding Claim 29, Applicant presents the same discussion as above regarding the independent Claim 19 on which dependent Claim 29 is based.

Regarding Claim 19 (and hence dependent claim 29), Iliff discloses a system that physically comprises *many discrete devices and systems*, such as personal computers, display monitors, modems and computer network hardware (Fig. 25a). A "tele-stethoscope" is disclosed as *part of a larger system*, whereby the stethoscope is connected to a computer system. Iliff makes no suggestion that his invention can be or should be embodied in a "wearable" device (the scope of Claim 19) such as a stethoscope, *teaching away from such an integrated approach in favor of a computer system with separate elements*. Bredesen does not suggest a drug interaction database as claimed in Claim 29.

Bredesen in combination with Iliff suggests a stethoscope connected to a comprehensive multi-component computer which has various software functions. There is therefore no connection of suggestion to anyone skilled in the art that Iliff and Bredesen suggest a wearable stethoscope with drug interaction database.

Regarding Claim 32, Examiner states that Bredesen teaches an electronic stethoscope with *expanded physiological measurement capability*. Examiner then acknowledges that Bredesen does not explicitly disclose additional physiological measurement means. Applicant agrees with the latter statement, and respectfully finds no reference in Bredesen to expanded measurement capability. Bredesen is clearly limited to the measurement of body sounds as the sole physiological measurement.

"wearable around the neck or shoulders of an operator" (Claim 32) -

Regarding wearability, Bredesen makes no claim that his invention is wearable, and without reference to the physical size of the computing and display means, it is not clear that Bredesen's invention is wearable. The scale of Bredesen Figure 1 certainly does not suggest "wearable on the neck or shoulders" as in Claim 32.

"housing provides a unified portable platform for carrying all said elements" (Claim 32) -

Considering the combination of Iliff and Bredesen, Iliff discloses a system comprising *multiple elements*, such as a *computer, display and other elements typical of a computer system solution* that might make multiple measurements. There is no suggestion in Iliff that the system can be embodied in a "wearable" stethoscope or a "unified portable platform", but rather would require a desk filled with separate instruments and computers.

"Additional physiological measurement means" (Claim 32) -

Bredesen makes no reference to multiple physiological measurements, addressing solely auscultation (body sounds).

Taken in combination, Bredesen and Iliff therefore do not suggest a unified wearable stethoscope with multiple physiological measurements.

"wherein additional physiological measurements are physically removable from said housing" (Claim 33) -

(Clarification of References: Regarding Claim 33, Examiner cites Bredesen Column 51. However, Bredesen has only 46 Columns. Applicant is therefore unable to address the discussion in the context of the reference. Applicant responds with reference to the entire Bredesen patent).

Regarding Claim 33, Bredesen discloses acquiring sounds from the body as the only measurement, making no mention of multiple physiological measurements. Bredesen further makes no mention of *modularity* in adding measurement capability. Iliff does not address or suggest a modular unified system, teaching a multi-component system. Applicant therefore

respectfully finds no reference, suggestion or teaching in Bredesen and Iliff that suggest Claim 33.

8. "Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Iliff U.S. Patent 6,236,862, and further in view of Plesko U.S. 5,880,452."

(Clarification of References: Examiner associates Iliff with U.S. Patent 6,236,862. However U.S. 6,236,862 is Erten, which mentions the word "stethoscope" but whose subject matter is unrelated to the present invention. It is assumed that the Examiner refers to Erten.)

"barcode reader" (Claim 30) -

Regarding Claim 30, as discussed above, Bredesen does not teach the electronic stethoscope of Claim 19, and hence Claim 29, dependent on Claim 19. Neither Iliff nor Erten mentions a barcode reader. While Plesko does disclose a barcode function, Claim 30 is dependent on Claims 19 and 29, neither of which is suggested by the prior art. Plesko's reference to a barcode reader fails to teach the single "portable housing" or "wearable" stethoscope. It is thus proposed that numerous, unsuggested multiple steps are required to develop the present invention given the cited prior art.

9. "Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Such U.S. Patent 5,457,751."

"A miniature virtual display device which provides information display by placing the eye close to the display screen and viewing a virtual image" (Claim 34) -

Examiner correctly acknowledges that Bredesen does not teach a miniature visual display as claimed in Claim 34.

However, Examiner proposes that Such teaches an electro-optical miniature display consistent with Claim 34. Closer reading of the reference (Such, Col. 1 lines 43-48) reveal that Such actually uses the stethoscope to *teach away from the present invention, not to suggest it.* Such teaches that U-shaped headphones such as on a Stethoscope are undesirable platforms for a visual display system as

claimed in Claim 34. Such therefore mentions stethoscopes merely to dismiss their form or structure as being completely unsuited to virtual display applications.

The elements of Claim 34 are therefore not disclosed in the prior art, and the combination of Bredesen and Such teaches away from the invention as claimed.

10. "Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Plesko U.S. Patent 5,880,452."

"Additional patient information acquisition means" (Claim 35) -

Examiner correctly acknowledges that Bredesen does not disclose additional physiological measurement means or patient data acquisition means.

"unified portable platform" (Claim 35) -

Examiner cites Plesko as disclosing a stethoscope plugged into a barcode scanner terminal. The stethoscope and barcode scanner terminal of Plesko are separate physical devices (Plesko Figure 7), with the stethoscope being a peripheral to the terminal device. This teaches away from the method of Claim 35, in that Plesko teaches that systems can be built from independent devices that are housed independently and are powered independently. This is in contradiction to Claim 35 which claims a "unified portable platform" that is physically embodied in the same housing, controlled by a single processor, and powered by a single power source. To arrive at Claim 35 from Plesko, one is required to take multiple steps to integrate the devices, with an entirely different physical form factor and circuit design from that suggested.

The central thesis of Plesko's teaching is that data acquisition can be achieved via a PCMCIA card to which external devices are connected. To those skilled in the art, a PCMCIA-based architecture comprises separate peripheral devices or functions plugged into a central terminal or computer, such as a notebook computer. This is clearly shown in Plesko Figure 7. The PCMCIA approach is understood by those skilled in the art to suggest

peripherals attached to a computer, which is the opposite teaching to the integrated method of Claim 35.

11. "Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bredesen et al. U.S. Patent 5,010,889 (herinafter, "Bredesen") in view of Grasfield et al. U.S. Patent 5,825,895 (herinafter, "Grasfield")."

"Second audio input means for detecting voice sounds" (Claim 36) -

Examiner acknowledges that Bredesen does not disclose a second input for detecting voice.

Examiner states that Grasfield discloses a microphone (54, Fig. 8) for detecting voice sound (Col. 6, lines 49-56). However a close reading of the specification and drawing in Grasfield indicates that the purpose of microphone 54 is to detect body sounds for the normal stethoscope purpose of detecting body sounds and patient examination (auscultation). Grasfield makes no suggestion that the microphone can or should detect voice signals, and examination of Figure 8 shows a microphone that is not positioned for detecting any sound other than that traveling up the stethoscope tubes, which are not voice sounds but body sounds. Examiner reference Grasfield Col. 1 lines 59-60 discloses "improved performance" as a "stethoscope". Stethoscopes are intended to detect heart and lung sounds, not voice signals. Grasfield simply does not address the same subject matter as the present invention as in Claim 36. Voice detection is simply not disclosed in Grasfield.

As stated, Examiner notes that Bredesen does not teach a second input, and as explained above, Grasfield does not teach a voice microphone. The combination of these two prior art references therefore do not teach nor suggest the critical elements of Claim 36.

SUMMARY - Response to Rejections of Claims 19-36

Applicant submits that the central reference, Bredesen, does not teach the core elements of the independent Claims 19, 32, 34, 35, and 36. Insofar as Bredesen discloses digital communications, this refers to patient measurements and patient records. The present invention claims program

or software download, entirely different from patient records. Regarding the dependent claims, even in combination with Bredesen, the cited references address subject matter unrelated to the subject matter of the present invention, teach away from the methods claimed in the present invention, or make no suggestion, independently or in combination, of the claimed invention.

While superficially, some of the *words used* in the cited references might *coincide* with the words used in the claims of the present invention, such that a *word search might suggest some correlation* to the claimed invention, analysis of the *content* of the prior art references reveals subject matter, methods, and teachings that are at great variance with the claims of the present invention.

Finally, adaptability of the stethoscope with respect to software changes and modularity are central to the novelty of the present invention. Such user-modification capability is counter-intuitive, given the nature of regulatory rules governing the design and deployment of medical devices. Those skilled in the art therefore consider software modification and other user-adaptation to be something to be avoided in the invention of medical devices.

For all the above reasons, it is submitted that the claimed invention defines over all of the references cited, individually or in combination, and allowances of the claims in this application is respectfully requested.

If the Examiner has any questions, he is invited to contact Colin Abrahams at 818-710-2788.

Applicant further requests an interview with Examiner, in the event that Examiner does not accept the arguments and analysis as presented herein. Applicant feels that an interview would efficiently provide the opportunity to clarify any further questions.

Respectfully submitted,

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